510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

EXHIBIT D

Regulatory Authority: Safe Medical Devices Act of 1990, 21 CFR 807.92

Company:

J.B.S. (USA), Inc.
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SEP 2 5 1996

K962757

Medical Device Establishment Registration #: 9681258

FDA Owner/Operator #: 9021265

Contact: Ms. Liza Burns, Regulatory Consultant

Trade Name: J.B.S. SPINE SYSTEM® WITH PEDICLE SCREWS

Common Name: Spinal Fixation Device

Classification Name: Spinal Pedicle Screw, Fixation, Appliance System

Classification Code: 87 MNH, KWP

Device Description: The J.B.S. Spine System ® implants are single-use temporary devices used to stabilize the lumbar and thoracic vertebrae, to promote fusion. The System is to be removed after fusion occurs. The J.B.S. Spine System ® consists of sacral screws, sacral plates, pedicle screws, rods, pedicle and laminar hooks and clamps, and linking plates. J.B.S. has both 5mm and 6mm rod systems. The implants are composed of surgical implant titanium, Ti 6Al 4V ELI, according to ASTM-136-92. Instruments used to implant the J.B.S. Spine System are made of Z30C13 stainless steel according to AFNOR Standard (corresponding to ASTM grade 420B stainless steel) with a polymer handle, or surgical implant titanium, Ti 6Al 4V ELI.

Indications for Use: When used as a non cervical hook and sacral screw system, the J.B.S. Spine System is indicated for use in patients with degenerative disc disease (discogenic back pain with degeneration of the disc confirmed by radiographic studies), spondylolisthesis, kyphosis, neurological scoliosis, spine tumors, spinal stenosis, patients with previously failed back surgeries, and fractures. When used as a pedicle screw system, it is intended for patients (a) having severe spondylolisthesis (grades 3 and 4) at the L5-S1 joint, who are receiving fusion using autogenous bone graft only, (c) who are having the device fixed or attached to the lumbar and sacral spine, and (d) who are having the device removed after development of a solid fusion mass. The J.B.S. Spine System, as a whole, is intended for posterior fixation from levels T1 through S1. The Sacral Plates are intended for posterior sacral fixation at S1 and S2. Levels of pedicle screw fixation are posterior fixation from levels L3 to through S1 only.

Contraindications: The J.B.S. Spine System is not to be used in patients with active localized or systemic infection, patients who are pregnant, or patients who have a disease or other medical condition which inhibits the potential of bony fusion (such as osteoporosis, kidney dialysis). When used as a pedicle fixation system additional contraindications include those patients receiving fusion using allograft, insertion of the screws into the pedicles to facilitate spinal fusion above the L5-S1 intervertebral joint, fixation of the pedicle screws to the cervical, thoracic, or lumbar spine, except for in cases of severe spondylolisthesis as described above, and/or in patients with stable spines.

Warnings, Precautions and Potential Adverse Effects: The surgeon should be thoroughly familiar with spinal instrumentation and the use of this system. All implants and instruments are packaged and supplied non-sterile. Prior to use, each implant must be sterilized according to the directions provided in this insert. The implant is designed for single patient use only and must never be reused. An explanted metal implant must never be reimplanted. Dissimilar metals in contact with each other can accelerate the corrosion process due to galvanic corrosion effects. Therefore, do not use components from other manufacturers when using the J.B.S. Spine System implants. This system is not to be used for anterior or anterolateral fixation. When used as a pedicle screw system, the J.B.S. Spine System is intended only for Grades 3 or 4 Spondylolisthesis at the fifth lumbar-first sacral (L5-S1) vertebral joint. The screws of the J.B.S. Spine System are not intended for insertion into the pedicles to facilitate spinal fusion above the L5-S1 intervertebral joint. The J.B.S. Spine System is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine, except for severe spondylolisthesis, as described above. The benefits of spine fusion using any brand of pedicle screw fixation system have not been sufficiently established in patients with stable spines. Possible risks identified with the use of the J.B.S. Spine System, which may require additional surgery include (but are not limited to): vertebral fracture, fracture of the device components, neurological damage, vascular and/or visceral injury, loss of fixation, bleeding, infection, scar tissue formation, leakage of cerebrospinal fluid, and damage to the surrounding soft tissue. Also included are risks associated with the use of general anesthesia. Risks specifically associated with spinal instrumentation include nerve root or spinal cord impingement resulting from poorly positioned screws or from bone fragments, and bone resorption and/or loosening of the implant.

Substantially Equivalent Devices: 1. TSRH System by Sofamor Danek 2. PLSA System by Advanced Spine Fixation Systems 3. Rogozinsky System by Richards 4. Harrington System by Zimmer 5. C-D System by Stuart (Danek).

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